AMENDED IN ASSEMBLY AUGUST 18, 2014 AMENDED IN ASSEMBLY JUNE 4, 2014 AMENDED IN SENATE APRIL 7, 2014

SENATE BILL

No. 906

Introduced by Senator Correa

January 21, 2014

An act to add Section 1256.01 to the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 906, as amended, Correa. Elective Percutaneous Coronary Intervention (PCI)-Offsite Program.

Existing law establishes, until January 1, 2015, the Elective Percutaneous Coronary Intervention Pilot Program in the State Department of Public Health, which authorizes up to 6 eligible acute care hospitals that are licensed to provide cardiac catheterization laboratory service in California, and that meet prescribed, additional criteria, to perform scheduled, elective primary percutaneous coronary intervention (PCI), as defined, for eligible patients. Existing law establishes an advisory oversight committee to oversee, monitor, and make recommendations to the department concerning the pilot program. Existing law also imposes various reporting requirements on the advisory oversight committee and the department, including recommendations as to whether the pilot program should be continued or terminated and whether elective PCI without onsite cardiac surgery should be continued in California.

This bill would create the Elective Percutaneous Coronary Intervention Offsite Program in the State Department of Public Health to certify an

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unlimited number of general acute care hospitals that are licensed to provide urgent and emergent cardiac catheterization laboratory service in California, and that meet prescribed, additional criteria, to perform scheduled, elective PCI. The bill would authorize a hospital that was participating in the Elective PCI Pilot Program as of December 31, 2014, to continue to perform elective PCI-provided that the hospital obtains, but would require the hospital to obtain a certification under the bill's provisions by January 1, 2016. The bill would require the Office of Statewide Health Planning and Development to annually develop and make available to the public a report regarding each participating hospital's performance on mortality, stroke rate, and emergency coronary artery bypass graft rate and would authorize the department to form an advisory oversight committee for the purpose of analyzing those reports and recommending changes to the data to be included in the reports. The bill would also authorize the department to charge each participating hospital a supplemental licensing fee not to exceed the reasonable cost to the department of overseeing the program.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1256.01 is added to the Health and Safety 2 Code, to read:
- Code, to read:
 1256.01. (a) The Elective Percutaneous Coronary Intervention
- 4 (PCI)—Offsite Program is hereby established in the department.
 5 The purpose of the program is to allow the department to certify
- 6 general acute care hospitals that are licensed to provide urgent and
- emergent cardiac catheterization laboratory service in California,
- 8 and that meet the requirements of this section, to perform 9 scheduled elective percutaneous transluminal coronary angioplasty
 - scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients.
- and stent placement for eligible patients.
 (b) For purposes of this section, the following terms have the
- 12 following meanings: 13 (1) "Certified hospital" means an eligible hospital that is
- 14 certified by the department to participate in the Elective 15 Percutaneous Coronary Intervention (PCI) Program established
- 16 by this section.
- 17 (1)

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(2) "Elective Percutaneous Coronary Intervention (elective PCI)" means scheduled percutaneous transluminal coronary angioplasty and stent placement. Elective PCI does not include urgent or emergent PCI that is scheduled on an ad hoc basis.

(2)

- (3) "Eligible hospital" means a general acute care hospital that has a licensed an approved cardiac catheterization laboratory, does not have onsite cardiac surgery, and is in substantial compliance with all applicable state and federal licensing laws and regulations.
- (4) "Interventionalist" means a licensed cardiologist who meets the requirements for performing elective PCI at an offsite hospital. PCI.
- (4) "Offsite hospital" means a hospital participating in the Elective Percutaneous Coronary Intervention (PCI) Offsite Program established by this section.
- (c) To participate in the Elective PCI—Offsite Program, an eligible hospital shall obtain certification from the department and shall meet all of the following requirements:
- (1) Demonstrate that it complies with the recommendations of the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology Foundation, and the American Heart Association, for performance of PCI without onsite cardiac surgery, as those recommendations may evolve over time.
- (2) Provide evidence showing the full support from hospital administration in fulfilling the necessary institutional requirements, including, but not limited to, appropriate support services such as respiratory care and blood banking.
- (3) Participate in, and provide timely submission of data to, the American College of Cardiology-National Cardiovascular Data Registry.
- (4) Confer rights to transfer the data submitted pursuant to paragraph (3) to the Office of Statewide Health Planning and Development.
- (5) Any additional requirements the department deems necessary to protect patient safety or ensure quality of care.
- (d) An eligible hospital shall submit an application to the department *pursuant to Section 1265* to obtain certification to participate in the Elective PCI-Offsite Program. The application shall include sufficient information to demonstrate compliance

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with the standards set forth in this section, and shall also include the effective date for initiating elective PCI service, the general service area, a description of the population to be served, a description of the services to be provided, a description of backup emergency services, the availability of comprehensive care, and the qualifications of the general acute care hospital providing the emergency treatment eligible hospital. The department may require that additional information be submitted with the application. Failure to submit any required criteria or additional information shall disqualify the applicant from the application process and from consideration for participation in the program. The department may deny an Elective PCI Program applicant pursuant to Article 2 (commencing with Section 1265).

- (e) An eligible hospital that, as of December 31, 2014, was participating in the Elective Percutaneous Coronary Intervention Pilot Program established under Chapter 295 of the Statutes of 2008, as amended by Chapter 202 of the Statutes of 2013, may continue to perform elective PCI and shall be considered an offsite a certified hospital provided that the until January 1, 2016. On and after January 1, 2016, a hospital described in this subdivision shall not be considered a certified hospital unless the hospital obtains has obtained a certification under this section by January 1, 2016.
- (f) The Office of Statewide Health Planning and Development shall, using the data transferred pursuant to paragraph (4) of subdivision (c), annually develop and make available to the public a report regarding each offsite certified hospital's performance on mortality, stroke rate, and emergency coronary artery bypass graft rate.
- (g) The department may establish an advisory oversight committee composed of two interventionalists from offsite certified hospitals, two interventionalists from general acute care hospitals that are not-offsite certified hospitals, and a representative of the department, for the purpose of analyzing the report issued under subdivision (f) and making recommendations for changing the data to be included in future reports issued under subdivision (f).
- (h) If at any time an offsite a certified hospital fails to meet the criteria set forth in this section for being an offsite a certified hospital or fails to safeguard patient safety, as determined by the department, the department may suspend or revoke, pursuant to

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Section 70309 of Title 22 of the California Code of Regulations, the certification issued to that offsite hospital under this section. An offsite A hospital whose certification is revoked pursuant to this subdivision may request an appeal with the department and is not precluded from reapplying for certification under this section.

- (i) The department may charge offsite certified hospitals a supplemental licensing fee, the amount of which shall not exceed the reasonable cost to the department of overseeing the program.
- (j) The department may contract with a professional entity with medical program knowledge to meet the requirements of this section.